Notice of Allowability	Application No.	Applicant(s)	
	09/871,212	TIKOO ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *June 25, 2003*.

2. ☒ The allowed claim(s) is/are *1-55 and 64-72*.

3. ☒ The drawings filed on *10/5/01; 10/7/02; 6/10/03* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 25, 2004 has been entered.

The Amendment filed June 25, 2004 in response to the Office Action of August 27, 2003 is acknowledged and has been entered.

The prior rejections are withdrawn in view of Applicant's submission of the 37 C.F.R. 1.132 declaration (Katz declaration) by Dr. Tikoo.

Linking claims 1 and 22 are allowed. Since the restriction requirement among inventions of Group I-IV, as set forth in the Office action mailed on September 6, 2002 (Paper No. 11), was conditioned on the nonallowance of the linking claim(s), **the restriction requirement as to the linked inventions is hereby withdrawn**. Claim 3, 4, 7, 8, 18-20, 23, 24, 26, 36-40, 44, 45, 52-54, previously withdrawn from consideration as a result of the restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. In view of the withdrawal of the restriction requirement as to the linked inventions, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable linking claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are

no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 1-28, 35-54 and 64-72 directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 29-34 and 55-63 hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Office action mailed on September 6, 2002 (Paper No. 11) is hereby withdrawn.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Debra J. Glaister on September 17, 2003.

Please amend the claims as follows:

Claim 1 (Currently Amended): A <u>recombinant</u> bovine adenovirus vector comprising a modification in a polynucleotide encoding a capsid protein, or fragment thereof, wherein said capsid protein, or fragment thereof, is associated with tropism and wherein said modification is associated with altered tropism.

Claim 2 (Previously Presented): The adenovirus vector of claim 1 wherein said polynucleotide encoding a capsid protein, or fragment thereof, is replaced with a polynucleotide encoding a heterologous mammalian adenovirus capsid protein, or fragment thereof.

Claim 3 (Original): The adenovirus vector of claim 1 wherein said capsid protein, or fragment thereof, is a penton protein, or fragment thereof.

Claim 4 (Original): The adenovirus vector of claim 1 wherein said capsid protein, or fragment thereof, is a hexon protein, or fragment thereof.

Claim 5 (Original): The adenovirus vector of claim 1 wherein said capsid protein, or fragment thereof, is a fiber protein, or fragment thereof.

Claim 6 (Previously Presented): The adenovirus vector of claim 5 wherein the fiber protein, or fragment thereof, comprises the knob region of a fiber protein.

Claim 7 (Previously Presented): The adenovirus vector of claim 3 wherein said polynucleotide encoding the penton protein, or fragment thereof, is replaced with at least one polynucleotide encoding a heterologous mammalian adenovirus penton protein, or fragment thereof.

Claim 8 (Previously Presented): The adenovirus vector of claim 4 wherein said polynucleotide encoding the hexon protein, or fragment thereof, is replaced with at least one polynucleotide encoding a heterologous mammalian adenovirus hexon protein, or fragment thereof.

Claim 9 (Previously Presented): The adenovirus vector of claim 5 wherein said polynucleotide encoding the fiber protein, or fragment thereof, is replaced with at least one

polynucleotide encoding a heterologous mammalian adenovirus fiber protein or fragment thereof.

Claim 10 (Original): The adenovirus vector of claim 2 wherein said heterologous mammalian adenovirus capsid protein, or fragment thereof, includes porcine, ovine, canine or human adenovirus capsid protein, or fragment thereof.

Claim 11 (Original): The adenovirus vector of claim 10 wherein said heterologous mammalian adenovirus capsid protein, or fragment thereof, is a human adenovirus capsid protein, or fragment thereof.

Claim 12 (Original): The adenovirus vector of claim 1 wherein said adenovirus is a sub-type 1 adenovirus.

Claim 13 (Original): The adenovirus vector of claim 1 wherein said adenovirus is a sub-type 2 adenovirus.

Claim 14 (Original): The adenovirus vector of claim 12 wherein said adenovirus vector is BAV3.

Claim 15 (Previously Presented): The adenovirus vector of claim 14 wherein said modification in a polynucleotide encoding a capsid protein, or fragment thereof, is a replacement of a polynucleotide encoding a BAV3 fiber protein, or fragment thereof, with a polynucleotide encoding a heterologous mammalian adenovirus fiber protein, or fragment thereof.

Claim 16 (Previously Presented): The adenovirus vector of claim 15 wherein said mammalian adenovirus fiber protein, or fragment thereof, includes bovine, porcine, ovine, canine or human adenovirus fiber protein, or a fragment thereof.

Claim 17 (Original): The adenovirus vector of claim 16 wherein said mammalian adenovirus fiber protein is a human adenovirus fiber protein.

Claim 18 (Original): The adenovirus vector of claim 1 wherein said vector lacks E1 function.

Claim 19 (Original): The adenovirus vector of claim 18 wherein said vector has a deletion of part or all of the E1 gene region.

Claim 20 (Original): The adenovirus vector of claim 1 wherein said vector has a deletion of part or all of the E3 gene region.

Claim 21 (Original): The adenovirus vector of claim 1 wherein said vector further comprises a polynucleotide encoding a heterologous protein.

Claim 22 (Previously Presented): The adenovirus vector of claim 21 wherein said heterologous protein includes cytokines; lymphokines; membrane receptors recognized by pathogenic organisms; dystrophins; insulin; proteins participating in cellular ion channels; antisense RNAs; proteins capable of inhibiting the activity of a protein produced by a pathogenic gene; a protein inhibiting an enzyme activity; protein variants of pathogenic proteins; antigenic epitopes; major histocompatibility complex classes I and II proteins; antibodies; immunotoxins; toxins; growth factors or growth hormones; cell receptors or their ligands; tumor suppressors; cellular enzymes; or suicide genes.

Claim 23 (Original): The adenovirus vector of claim 22 wherein said polynucleotide encoding said heterologous protein is inserted in the adenovirus E1 gene region.

Claim 24 (Original): The adenovirus vector of claim 22 wherein said polynucleotide encoding said heterologous protein is inserted in the adenovirus E3 gene region.

Claim 25 (Original): The adenovirus vector of claim 1 wherein said vector is replication-competent.

Claim 26. (Original): The adenovirus vector of claim 1 wherein said vector is replication-defective.

Claim 27 (Original): A host cell comprising the bovine adenovirus vector of claim 1.

Claim 28 (Original): A host cell comprising the bovine adenovirus vector of claim 21.

Claim 29 (Currently Amended): A method of producing a recombinant bovine adenovirus vector comprising a modification in a polynucleotide encoding a capsid protein, or a fragment thereof, comprising the steps of, obtaining a bovine adenovirus vector~~; and introducing~~ ~~a~~ comprising a modification ~~into~~ in a polynucleotide encoding a capsid protein, or fragment thereof, wherein said capsid protein, or fragment thereof, is associated with tropism and wherein said modification is associated with altered tropism, and culturing the adenovirus vector under conditions suitable for production of the bovine adenovirus vector.

Claim 30 (Original): The method of claim 29 wherein said capsid protein, or fragment thereof, is a penton protein, or fragment thereof.

Claim 31 (Original): The method of claim 29 wherein said capsid protein, or fragment thereof, is a hexon protein, or fragment thereof.

Claim 32 (Original): The method of claim 29 wherein said capsid protein, or fragment thereof, is a fiber protein, or fragment thereof.

Claim 33 (Original): The method of claim 29 wherein said adenovirus vector further comprises a polynucleotide encoding a heterologous protein.

Claim 34 (Original): The method of claim 29 wherein said bovine adenovirus is a sub-type 1 bovine adenovirus.

Claim 35 (Original): A recombinant bovine adenovirus comprising a modification in a polynucleotide encoding a capsid protein, or fragment thereof, wherein said capsid protein, or fragment thereof, is associated with tropism and wherein said modification is associated with altered tropism.

Claim 36 (Original): The recombinant adenovirus of claim 35 further comprising a polynucleotide encoding a heterologous protein.

Claim 37 (Original): The recombinant adenovirus of claim 36 wherein said polynucleotide encoding said heterologous protein is inserted in the adenovirus E1 gene region.

Claim 38 (Original): The recombinant adenovirus of claim 36 wherein said polynucleotide encoding said heterologous protein is inserted in the adenovirus E3 gene region.

Claim 39 (Original): The recombinant adenovirus of claim 35 wherein said capsid protein, or fragment thereof, is a penton protein, or fragment thereof.

Claim 40 (Original): The recombinant adenovirus of claim 35 wherein said capsid protein, or fragment thereof, is a hexon protein, or fragment thereof.

Claim 41 (Original): The recombinant adenovirus of claim 35 wherein said capsid protein, or fragment thereof, is a fiber protein, or fragment thereof.

Claim 42 (Previously Presented): The recombinant adenovirus of claim 41 wherein the fiber protein, or fragment thereof comprises the knob region of a fiber protein.

Claim 43 (Currently amended): An immunogenic composition comprising a recombinant bovine adenovirus wherein said adenovirus comprises a modification in a polynucleotide encoding a capsid protein, or fragment thereof, and wherein said capsid protein, or fragment thereof, is associated with tropism and wherein said modification is associated with altered tropism.

Claim 44 (Original): The immunogenic composition of claim 43 wherein said capsid protein is a penton protein, or fragment thereof.

Claim 45 (Original): The immunogenic composition of claim 43 wherein said capsid protein is a hexon protein, or fragment thereof.

Claim 46 (Original): The immunogenic composition of claim 43 wherein said capsid protein is a fiber protein, or fragment thereof.

Claim 47 (Previously Presented): The immunogenic composition of claim 46 wherein said fiber protein, or fragment thereof, comprises the knob region of a fiber protein.

Claim 48 (Previously Presented): The immunogenic composition of claim 43 wherein said modification in a polynucleotide encoding a capsid protein or fragment thereof is a replacement of a polynucleotide encoding a bovine fiber protein, or fragment thereof, with a polynucleotide encoding a mammalian adenovirus fiber protein, or fragment thereof.

Claim 49 (Previously Presented): The immunogenic composition of claim 48 wherein said mammalian adenovirus fiber protein, or fragment thereof, is a human adenovirus fiber protein, or fragment thereof.

Claim 50 (Original): The immunogenic composition of claim 43 wherein said bovine adenovirus is a sub-type 1 adenovirus.

Claim 51 (Original): The immunogenic composition of claim 50 wherein said bovine adenovirus is BAV3.

Claim 52 (Original): The immunogenic composition of claim 43 wherein said bovine adenovirus comprises a polynucleotide encoding a heterologous protein.

Claim 53 (Original): A pharmaceutical composition capable of inducing an immune response in a mammalian subject, said composition comprising the immunogenic composition of claim 52.

Claim 54 (Original): The pharmaceutical composition of claim 53 further comprising a pharmaceutically acceptable excipient.

Claim 55 (Currently Amended): A method for eliciting an immune response in a mammalian host ~~to protect against infection~~, the method comprising administration of the pharmaceutical composition of claim 54 to the mammalian host, wherein said heterologous protein comprises an antigenic epitope.

Cancel Claims 56-63

Claim 64 (Previously Presented): A composition comprising the adenovirus vector of claim 1.

Claim 65 (Previously Presented): A composition comprising the adenovirus vector of claim 5.

Claim 66 (Previously Presented): A composition comprising the adenovirus vector of claim 21.

Claim 67 (Previously Presented): A composition comprising the adenovirus of claim 35.

Claim 68 (Previously Presented): A composition comprising the adenovirus of claim 41.

Claim 69 (Previously Presented): The immunogenic composition of claim 48 wherein said mammalian adenovirus fiber protein, or fragment thereof, includes porcine, ovine, canine or human adenovirus capsid protein, or fragment thereof.

Claim 70 (Previously Presented): A host cell comprising the adenovirus vector of claim 5.

Claim 71 (Previously Presented): A host cell comprising the adenovirus of claim 35.

Claim 72 (Previously Presented): A host cell comprising the adenovirus of claim 41.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 9/17/04